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July 18, 2025

The Honorable Zahid N. Quraishi
U.S. District Court for the District of New Jersey
402 East State Street
Trenton, NJ 08608

Re: *Kirk Osterman v. Novo Nordisk A/S et al.*, No. 3:25-CV-03500,
Novo Nordisk's Pre-Motion Letter Regarding Motion to Dismiss

Dear Judge Quraishi:

Pursuant to the Court's guidelines, Defendants Novo Nordisk Inc. and Novo Nordisk A/S (collectively, Novo Nordisk) respectfully request leave to file a motion to dismiss Plaintiff's Complaint, as the Court permitted in the *Kane* matter, No. 24-CV-11384 (D.N.J.). In the alternative, Novo Nordisk requests a pre-motion conference to discuss their motion to dismiss.

Plaintiff Kirk Osterman, an Illinois resident, alleges that he used Wegovy® (semaglutide) between June 2023 and June 2024. Plaintiff claims he developed NAION and its sequelae. *See* Complaint, Dkt. 1 ("Compl.") ¶¶ 25-27. NAION is a condition caused by reduced blood flow to the optic nerve that can lead to vision loss. Plaintiff brings failure-to-warn claims, and he alleges that Novo Nordisk defectively designed Wegovy®, engaged in unspecified fraud and misrepresentation, and violated ill-defined express and implied warranties. Plaintiff does not identify where or when he developed NAION or where he was prescribed and used Wegovy®. Plaintiff seeks compensatory, economic, and punitive damages.

Wegovy® is a once-weekly prescription medicine indicated for chronic weight management. *Id.* ¶ 64. Wegovy® is part of a class of medicines known as glucagon-like peptide-1 receptor agonists (GLP-1RAs). *Id.* ¶ 48. GLP-1RA medicines have been on the market for two decades and, in that time, have revolutionized the treatment of type 2 diabetes and obesity. *See id.* ¶ 44. Wegovy® is the first weight management medication shown to reduce the risk of cardiovascular complications associated with obesity and overweight.

Non-Arteritic Anterior Ischemic Optic Neuropathy ("NAION") is the most common cause of sudden optic nerve-related vision loss. Risk factors for NAION include age over 50 years old, diabetes, male gender, hypertension, hyperlipidemia, and coronary heart disease, among others. The first study reporting a potential association between GLP-1RA medicines and NAION was published online in July 2024, after Plaintiff stopped taking Ozempic®. In October 2024, FDA opened

a "newly identified safety signal" (NISS)[1] related to a potential risk of NAION with GLP-1RA medicines.[2] In June 2025, FDA announced that, as part of its evaluation, it would be conducting a study within its Sentinel system to further assess the relationship between GLP-1RA therapy and NAION, if any.[3] FDA's evaluation of the potential signal is ongoing, and the Agency has not made any final determinations or taken any regulatory action with respect to any of the GLP-1RA medicines or their labeling.[4]

Since Plaintiff resides in Illinois, Novo Nordisk outlines its motion under Illinois law:

Design Defect. Plaintiff brings two design-defect claims—one based in negligence (Count IX) and the other in strict liability (Count X). These claims are preempted by federal law because any changes to the formulation or dosage of Wegovy® would require FDA pre-approval. *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 490 (2013). Because Novo Nordisk could not unilaterally change the design of its FDA-approved pharmaceutical product, Plaintiff's design-defect claims are preempted as a matter of law. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623-24 (2011).

Fraud and Misrepresentation. The Complaint fails to meet Rule 9(b)'s heightened pleading standard for fraud-based claims because Plaintiff does not allege the circumstances supporting his claims with particularity. *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 778 (3d Cir. 2018). Plaintiff makes broad, boilerplate assertions like "Defendants made material misrepresentations . . . regarding the safety and/or efficacy of Wegovy," Compl. ¶ 428, and "represented affirmatively" that "Wegovy was . . . safe and effective . . . despite the increased risks of NAION," *id.* ¶ 429. Accordingly, Plaintiff's numerous fraud and misrepresentation claims—fraudulent concealment/fraud by omission (Count V), fraudulent/intentional misrepresentation (Count VI), negligent misrepresentation/marketing (Count VII), and strict product liability misrepresentation/marketing (Count VIII)—should be dismissed.

Failure to Warn. This Court should dismiss Plaintiff's two failure-to-warn claims (Counts

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[1] A NISS refers to a potential safety signal identified based on review of data from FDA's Adverse Event Reporting System (FAERS). As FDA explains, "The appearance of a drug on [the NISS] list does not mean that FDA has concluded that the drug has the listed risk. It means that FDA has identified a *potential safety issue*, but it does not mean that FDA has identified a causal relationship between the drug and the listed risk. . . . If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions, including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk." FDA, *Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System*, available at https://tinyurl.com/5h5bb6vz.

[2] FDA, *Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System: Oct.-Dec. 2024*, available at https://tinyurl.com/57zn53u6. A similar evaluation is underway in Europe under the auspices of the European Medicines Agency (EMA).

[3] Sentinel Initiative, *Risk of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) Following Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Use in Patients with Type 2 Diabetes Mellitus*, available at https://tinyurl.com/2etrwtbs.

[4] *See supra* n.2.

I and II) to the extent they rely upon a purported duty for Novo Nordisk to warn Plaintiff directly or third parties besides his prescriber. Illinois law recognizes that, under the learned intermediary doctrine, a manufacturer of prescription medicines only has a duty to warn physicians of the product's known dangers. *Martin ex rel. Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 354 (Ill. 1996). This Court should dismiss Plaintiff's non-actionable allegations that Novo Nordisk owed a duty to warn him directly or to warn third parties like regulatory agencies and the general public.

Express Warranty. Plaintiff's express warranty claim fails to identify an actionable express warranty under Illinois law. In Count III, Plaintiff alleges that Novo Nordisk "expressly represented to Plaintiff and Plaintiff's prescribing healthcare providers that Wegovy was safe for chronic weight management in adults with an initial Body Mass index (BMI) of 30 kg/m2 or greater, or with a BMI of 27 kg/m2 or greater and at least one weight-related comorbid condition." Compl. ¶ 332. However, "safe" and "effective" are terms of art in the pharmaceutical context that are not deemed express warranties of absolute safety and efficacy. *See In re Avandia*, 588 F. App'x 171, 176-77 (3d Cir. 2014) (reasoning that courts adopting the Uniform Commercial Code "have refused to find the words 'safe and effective' to create an express warranty in the absence of representations that a drug was free from all harmful side effects or was absolutely harmless"). Generic allegations, like those here, do not constitute an actionable warranty. *Baldwin v. Star Sci., Inc.*, 78 F. Supp. 3d 724, 740 (N.D. Ill. 2015) (dismissing express warranty claim that was inadequately pleaded).

Negligence. Plaintiff's negligence claim repackages his failure-to-warn and design-defect claims, but also includes a string of conclusory allegations and a kitchen-sink of negligence theories that fail to state a claim. Because Plaintiff does not plead this count with any level of detail and it duplicates the earlier negligence-based counts, the Court should dismiss this redundant and barebones claim. *See, e.g.*, *Heisner ex rel. Heisner v. Genzyme Corp.*, No. 08-CV-593, 2008 WL 2940811, at *7 (N.D. Ill. July 25, 2008).

Negligent Undertaking. Plaintiff's claim for negligent undertaking (Count XII) is an attempt to plead around the learned intermediary doctrine. Claims premised on an alleged duty of Novo Nordisk to warn Plaintiff directly, or premised on a breach of that purported duty, are barred by the learned intermediary doctrine. *See Kasin v. Osco Drug, Inc.*, 728 N.E.2d 77, 79 (Ill. Ct. App. 2000). Moreover, Illinois courts interpret such duties narrowly, and the Complaint pleads no facts that would trigger the broad, amorphous duty to warn the Complaint seeks to impose upon Novo Nordisk. *Frye v. Medicare-Glaser Corp.*, 605 N.E.2d 557, 560 (Ill. 1992) (narrowly construing duty for negligent undertaking claim and holding that pharmacist does not undertake to warn of all potential side effects by placing a warning about "drowsy eyes" on a medication bottle).

More Definite Statement. Since the Complaint is unclear about where many of the relevant events occurred, Novo Nordisk intends to move for a more definite statement under Rule 12(e). *Thomas v. Indep. Tp.*, 463 F.3d 285, 301 (3d Cir. 2006), *abrogated in part by Pearson v. Callahan*, 555 U.S. 223 (2009) (discussing qualified immunity).

In conclusion, Novo Nordisk requests leave to file a motion to dismiss or, in the alternative, request a pre-motion conference with the Court.

Dated: July 18, 2025

/s/ Raymond M. Williams
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CERTIFICATE OF SERVICE

I hereby certify that, on July 18, 2025, a true and correct copy of the foregoing Novo Nordisk's Pre-Motion Letter Regarding Motion to Dismiss was electronically filed using the Court's CM/ECF system, causing notification of the filing to all counsel of record.

/s/ Raymond M. Williams
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